



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0198]

Belen G. Ngo; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Belen G. Ngo's (Ms. Ngo's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Ms. Ngo for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Ngo was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Ms. Ngo's debarment, FDA considered the relevant factors listed in the FD&C Act. Ms. Ngo failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Any application for termination of debarment by Ms. Ngo under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All applications must include the Docket No. FDA-2012-N-0198.

Received applications will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

“THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240-402-5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that: (1) the individual was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise

relating to the regulation of a drug product under the FD&C Act and (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs.

On September 6, 2011, in the U.S. District Court for the Eastern District of Virginia, Ms. Ngo pled guilty to a misdemeanor violation of the FD&C Act, namely failing to maintain records required by section 505(i) of the FD&C Act (21 U.S.C. 355(i)) in violation of sections 301(e) and 303(a)(1) (21 U.S.C. 331(e) and 333(a)(1)). Ms. Ngo's conviction stemmed from her actions as a clinical research coordinator for the Norfolk Diagnostic Center, doing business as Sentara Medical Group (Sentara). Eli Lilly Corp. (Eli Lilly) initiated a clinical study to investigate the effectiveness of lispro insulin for the purpose of applying for FDA approval to market lispro insulin for the treatment of Type 2 diabetes. Eli Lilly entered into an agreement with Sentara to conduct the ispro insulin study, and Sentara agreed to maintain records in accordance with 21 CFR 312.62(a) and by extension, section 505(i) of the FD&C Act. Ms. Ngo was a clinical research coordinator for the lispro insulin study and responsible for maintaining and completing case report forms (CRFs), which are the official records that document volunteers' participation in the study and contain vital medical information related to the performance of the study drug. Ms. Ngo knowingly and repeatedly falsified CRFs.

By letter dated April 27, 2012, FDA's Office of Regulatory Affairs (ORA) notified Ms. Ngo of its proposal to debar her for 5 years from providing services in any capacity to a person having an approved or pending drug product application. The proposal explained that the proposed debarment period was based on her misdemeanor conviction and that the maximum debarment period is 5 years. ORA explained that her conduct relating to the clinical trial relates to the development and approval, including the process for development and approval, of drug products; therefore, she was subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act.

The proposal outlined findings regarding the three applicable factors ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the

FD&C Act. ORA consider the nature and seriousness of the offense and the nature and extent of voluntary steps to mitigate the effect on the public as unfavorable factors for Ms. Ngo and weighed these factors against the absence of prior convictions involving matters within FDA's jurisdiction. ORA concluded, "Weighing all the factors, the Agency has determined that the unfavorable factors far outweigh the favorable factor, and therefore warrant the imposition of a five-year period of debarment in this case, the maximum possible period of debarment."

By letters dated May 22 and 23, 2012, through counsel, Ms. Ngo requested a hearing on the proposal. In her request for a hearing, Ms. Ngo acknowledges her conviction under Federal law and does not question the Agency's authority to debar her upon the basis of that conviction. However, Ms. Ngo argues that she should only be subject to a 1-year debarment, rather than FDA's proposed 5-year debarment, based on the considerations for determining the appropriateness and period of debarment under section 306(c)(3) of the FD&C Act. Ms. Ngo also included specific arguments related to the considerations under section 306(c)(3) of the FD&C Act.

Under the authority delegated by the Commissioner of Food and Drugs, the Chief Scientist has considered Ms. Ngo's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (*see* 21 CFR 12.24(b)).

The Chief Scientist has considered Ms. Ngo's arguments and concluded that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In support of her hearing request, Ms. Ngo makes many statements seemingly related to the nature and seriousness of her offense. Ms. Ngo first argues that the prosecution's failure to pursue a felony conviction reflects its judgment that a misdemeanor conviction and the terms of her probation or supervised release, which included an agreement not to engage in clinical

research during that period, are sufficient to protect the public health. Ms. Ngo next argues that her role was too small to have a significant effect on the study's results and that, because of her "minimal role" in providing data, the maximum debarment period is not appropriate. Ms. Ngo states that her study was discontinued and Eli Lilly did not use any of her information "in a detrimental way." Ms. Ngo also alleges that "[t]here is no evidence that her data affected the studies or resulted in the production of the drugs affected by the fraud" and that "[t]he drugs produced were free of fraud and material false statements." Ms. Ngo then asserts that her lack of financial motive for conducting her offense weighs in her favor because "the maximum period of debarment should be reserved for those who profit."

In determining the period of Ms. Ngo's debarment, whether she could have been convicted of a felony is not relevant. Under section 306(c)(3) of the FD&C act, FDA considers the nature and seriousness of the offense. Ms. Ngo admitted to knowingly and repeatedly falsifying clinical trial records. Additionally, the inclusion of a provision in Ms. Ngo's plea agreement that prevents her from engaging in clinical research "during any term of probation or supervised release" evinces concern by the prosecution that she would continue to violate the law if involved in clinical research.

As set forth in the proposal to debar, "[t]he creation and submission of falsified clinical trial data undermines FDA's determination of safety, effectiveness, and quality of the drugs the studies were designed to assess." Although the scope of conduct to which Ms. Ngo admitted during the criminal proceedings may have been limited to a few patients, submitting any false or fabricated data to the FDA is a serious offense that compromises the public health. Further, it is irrelevant that Eli Lilly ultimately did not use any of her information "in a detrimental way." Had Ms. Ngo's conduct gone undetected and Eli Lilly submitted a new drug application containing the falsified data, FDA might have relied on her fabricated information to approve a new drug product, which reliance could have compromised the public health. Additionally, Ms. Ngo's lack of financial gain from her conduct does not diminish the nature and seriousness of her

offense. Accordingly, Ms. Ngo has failed to create a genuine and material factual dispute with respect to the nature and seriousness of her offense.

Ms. Ngo next argues that, because she has not been involved in clinical trials since entering her guilty plea, there are “reasonable assurances” that “the offense will not happen again.” Ms. Ngo appears to be referencing the consideration under section 306(c)(3)(D) of the FD&C Act, where FDA must consider, *where applicable*, “whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future.” The considerations in section 306(c)(3) of the FD&C Act are not only for individuals but also for corporations, partnerships, and associations subject to permissive debarment. The consideration at issue does not typically apply to individuals because individuals are incapable of changes in ownership or management and could only alter the current operations of a business enterprise in which they are currently engaged. Even assuming for the sake of argument that an individual could point to changes in his or her current business practices as an applicable consideration under section 306(c)(3) of the FD&C Act, Ms. Ngo offers no actual facts to support her assertion that there are reasonable assurances that the offense will not occur again in the future; therefore, her unsubstantiated contention that, because she has not been involved in clinical trials since entering her guilty plea provides reasonable assurances that she will not commit the offense again, fails to create a genuine and substantial issue of fact that warrants a hearing.

Finally, Ms. Ngo argues that the maximum period of debarment is inappropriate for first-time offenders. While the Agency does consider prior convictions involving matters within the FDA’s jurisdiction under section 306(c)(3)(F) of the FD&C Act, that consideration is only one of several that FDA considers in determining the appropriateness and period of debarment under section 306(c)(3). Ms. Ngo knowingly and repeatedly falsified clinical data records. FDA has determined that the conduct underlying her offense, combined with her failure to take any voluntary steps to mitigate the effect of her offense on the public, is sufficiently serious to

warrant a 5-year period of debarment, even though she does not have any prior convictions involving matters within the Agency's jurisdiction.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under the authority delegated to her by the Commissioner of Food and Drugs, finds: (1) that Ms. Ngo has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) that the conduct underlying the conviction undermines the process for the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Ms. Ngo is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 335, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] (*see* 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Ms. Ngo, in any capacity during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Ngo, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, that person will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Ngo during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: July 27, 2021.

Denise Hinton,

Chief Scientist.

